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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/635,386  | 08/06/2003  | Mack J. Schermer     | 101117-0066C1       | 1202             |
| 24267   | 7590        | 10/04/2004           | EXAMINER            |                  |
| CESARI AND MCKENNA, LLP<br>88 BLACK FALCON AVENUE<br>BOSTON, MA 02210 |             |                      | BHATNAGAR, ANAND P  |                  |
|   |             | ART UNIT             |                     | PAPER NUMBER     |
|   |             |                      |                     | 2623             |
| DATE MAILED: 10/04/2004   |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/635,386             | SCHERMER ET AL.     |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Anand Bhatnagar        | 2623                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 06 August 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1, 3, 4, 13, and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 6,631,211 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because "the determining the locations of various sets of one or more boundaries that segment the scatter plot into pluralities of regions" of applicant's instant invention is read as the boundaries segmenting the data and denoting the points outside of the boundaries of claim 16 of U.S. patent 6,631,211 B1. The region of interest is read as the points located outside the boundaries. Regarding the feature of, retrieving the points from a computer file, is obvious to one skilled in the art to perform since the data is being stored in a computer file for current as well as future use.

Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 6,631,211 B1 in view of Peck et al. (U.S. patent 6,218,114 B1). Schermer et al. discloses to obtain data points and to display these points as a scatter plot. Schermer et al. does not disclose to have these obtained data points be points relating to gene information. Peck et al. teaches to perform a scatter plot of gene information (Peck et al.; col. 2 lines 63-66). It would have been obvious to one skilled in the art to combine the teaching of Peck et al. to that of Schermer et al. because they are analogous in performing scatter plot analysis. One in the art would have been motivated to incorporate the teaching of Peck et al. into the system of Schermer et al. in order to monitor expression of a large number of expressed genes in a simple inexpensive assay (Peck et al.; col. 1 lines 6-8).

Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23, 25, or 26 of U.S. Patent No. 6,631,211 B1.

Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 28 of U.S. Patent No. 6,631,211 B1. As for the genetic sample it is rejected for the same reason as claim 2 of the instant application above.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Regarding claims 7 and 12: The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These features of "superimposing the first set of one or more boundaries over the scatter plot displayed on the display unit, changing the visual properties of pairs of x-coordinates and y-coordinates displayed by the display unit in the first region of interest, removing the first set of one or more boundaries from the scatter plot displayed on the display unit and returning the visual properties of pairs of x-coordinates and y-coordinates in the first region of interest to their original visual properties, superimposing the second set of one or more boundaries over the scatter plot displayed by the display unit, and changing the visual properties of pairs of x-coordinates and y-coordinates displayed by the display unit in the second region of interest" are not enabled by the specifications. Examiner will address these claims as best understood.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A.) Claims 1, 3, 4, 5, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cline et al. (U.S. patent 5,458,126) and further in view of Gilham (U.S. patent 5,622,178).

Regarding claims 1, 3, 4, 13, and 14: A method for analyzing data (Cline et al.; fig. 4 blocks 21,23,25, etc.), the method comprising:  
producing and displaying a scatter plot that contains a plotted point for each of the data (Cline et al.; fig. 1 block 14 and 15, col. 3 lines 12-16 and 63-66);

determining the locations of various sets of one or more boundaries that segment the scatter plot into pluralities of regions that correspond to selection criteria interactively supplied by a user, with one or more of the sets defining at least one region of interest (Cline et al.; col. 3 lines 18-22, 24-28, and 45-51, wherein the region of interest is a group of points in the scatter plot);

recording information related to the data whose plotted points are located in a given region of interest (Cline et al.; fig. 1 blocks 51, 55, and 56, wherein the scatter points are stored in a memory/computer file);

selecting one or more plotted points in the given region of interest (Cline et al. fig. 1 elements 51 and 53, wherein the scatter points are stored in a memory and are selected to create a feature map); and

retrieving and displaying the recorded information corresponding to the one or more selected plotted points (Cline et al.; fig. 1 elements 51-61, wherein the scatter points are transformed into a feature map, after being retrieved from the storage unit, and then this information is displayed on the display unit, 61.

This feature map is read as information corresponding to the plotted points.).

Cline et al. discloses to create a scatter plot to measure the cardiac functionality. Cline et al. does not teach to interactively change the boundaries/thresholds in the scatter plot. Gilham teaches for an operator to choose the analysis and display parameters to be displayed (Gilham; col. 2 lines 48-59 and col. 3 lines 5-15 and 58-67, the selection of the parameters by the operator is read as performing it interactively). It would have been obvious to one skilled in the art to combine the teaching of Gilham to that of Cline et al. because they are analogous in creating cardiac scatter plots. One in the art would have been motivated to incorporate the teaching of Gilham to that of Cline et al. because in order to have a system and method of presenting scatter plot data in a manner that permits flexibility in the selection of analysis and display parameters (Gilham; col. 2 lines 2-6).

Regarding claim 5: The method wherein at least one boundary in the sets of one or more boundaries is derived based on one of the following:

- (i) a specified differential expression ratio calculated as the quotient of a variable associated with an x-axis and a variable associated with a y-axis (Cline et al.; fig. 3 and col. 2 lines 6-8), or
- (ii) a predetermined noise level, or
- (iii) statistics of the data (Cline et al.; Fig. 2 and 3, wherein the boundaries of the regions in fig. 3 are based on the statistics of the data obtained, shown in fig. 2), or
- (iv) a predetermined number of points are located outside the boundary.

B.) Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cline et al. (U.S. patent 5,458,126) and further in view of Peck (U.S. patent U.S. patent 6,218,114 B1).

Regarding claim 2: The method wherein the recorded information related to the data whose plotted points are located in the given region of interest is gene information.

Cline et al. discloses to create a scatter plot in order to determine the cardiac functionality. Cline et al. does not teach to perform a scatter plot of genes/genetic information. Peck et al. teaches to perform a scatter plot of genetic information (Peck et al.; col. 2 lines 63-66). It would have been obvious to one skilled in the art to combine the teaching of Peck et al. to that of Cline et al. because they are analogous in performing scatter plot analysis. One in the art would have been motivated to incorporate the teaching of Peck et al. into the

system of Cline et al. in order to monitor expression of a large number of expressed genes in a simple inexpensive assay (Peck et al.; col. 1 lines 6-8).

C.) Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cline et al. (U.S. patent 5,458,126), as modified by Gilham, further in view of Balaban (U.S. patent 6,308,170 B1), Laine et al. (U.S. patent 6,090,573), and Peck (U.S. patent U.S. patent 6,218,114 B1).

Regarding claim 6: It is rejected for the same reasons as claim 1 above and for the following limitations of:

a fluorescence reader that generates a pair of test-sample and control-sample fluorescence measurements for each of a plurality of genetic samples; a processor that receives the pairs of test-sample and control-sample fluorescence measurements generated by the fluorescence reader and produces a scatter plot graphing each test-sample fluorescence measurement against its corresponding control-sample fluorescence measurement.

Cline et al. discloses to display a scatter plot to determine cardiac functionality. Cline does not teach to use fluorescence nor teaches to show the test sample vs. a control sample scatter plot. Balaban teaches to plot two experiments on an x-y coordinate graph wherein the experiments to be graphed are chosen from a myriad of experiments (Balaban et al.; fig. 5I, col. 7 lines 15-25 and 60-67, and col. 8 lines 1-5). These experiments also include an experiment of genes from normal tissue, which is read as control samples, and

genes from diseased tissue, read as test samples. It would have been obvious to one skilled in the art to combine the teachings of Balaban to that of Cline et al. because they are analogous in scatter plotting. One in the art would have been motivated to incorporate the teaching of Balaban to that of Cline et al. in order to have an efficient and easy to use query system fro a gene expression database (Balaban; col. 2 lines 18-20).

Cline et al., as modified by Gilham and Balaban, gives a system wherein a scatter plot of a control sample vs. a test sample is being graphed as a scatter plot. Balaban further teaches to color code the points (Balaban; col. 8 lines1-4). Cline, Gilham, nor Balaban teach to obtain genetic information using fluorescence. Laine et al. teaches to use fluorescence on samples and graph a scatter plot of these samples (Laine et al.; fig. 2C and col. 4 lines 61-67). It would have been obvious to one skilled in the art to combine the teaching of Laine et al. to the system of Cline et al., as modified by Gilham and Balaban, because they are analogous in scatter plotting. One skilled in the art would have been motivated to combine the teaching of Laine et al. to the system of Cline et al., as modified by Gilham and Balaban, because in order to prevent the spread of disease, expedite treatment, and reduce costs associated with disease management (Laine et al.; col. 1 lines 25-28).

For the limitation of a genetic sample: see claim 2.

D.) Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cline et al. (U.S. patent 5,458,126), as modified by Gilham (U.S. patent 5,622,178), and further in view of Aghajan (U.S. patent 6,614,924 B1).

Regarding claims 7-12: They are rejected for the same reasons as claim 5 and as for the following limitations of:

superimposing the first set and second set of one or more boundaries over the scatter plot displayed on the display unit.

Cline et al., as modified by Gilham, discloses to display a scatter plot to determine cardiac functionality. Gilham further teaches wherein a user can select the data to be displayed as well as changing the display with different intensity of color (Gilham; col. 4 lines 1-5, this changing of the display is read as changing the visual properties of the graph). Neither Cline nor Gilham teaches to superimpose the boundary over the scatter plot. Aghajan teaches to superimpose the threshold on the display of the scatter plot (Aghajan; fig. 14 and col. 3 lines 1-4, wherein the threshold is read as the boundary). It would have been obvious to one skilled in the art to combine the teaching of Aghajan to that of Cline et al., as modified by Gilham, because they are analogous in scatter plotting. One skilled in the art would have been motivated to combine the teaching of Aghajan to that of Cline et al., as modified by Gilham, in order to define the threshold which would identify/group a certain amount of points or clusters in the scatter plot.

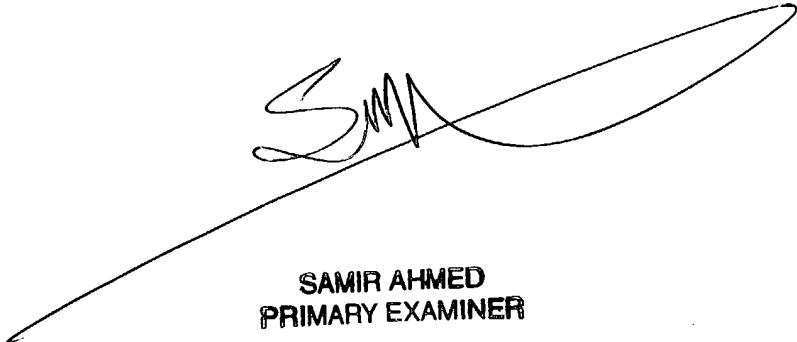
***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Friend et al. (U.S. patent 6,324,479 B1) for using gene expression profiles.

**Contact Information**

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand Bhatnagar whose telephone number is (703) 306-5914, whose supervisor is Amelia Au whose number is 703-308-6604, group fax is 703-872-9306, and Tech center 2600 customer service office number is 703-306-0377.



A handwritten signature in black ink, appearing to read "SAMIR AHMED", is written over a large, thin, curved line that slopes upwards and to the right. Below the signature, the name is printed in a standard font.

**SAMIR AHMED  
PRIMARY EXAMINER**

Anand Bhatnagar

Art Unit 2623

September 28, 2004